

Subject: Formulas and Other Enteral Nutrition Policy

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POLICY

OSU Health Plan covers oral nutrition (including special medical infant formulas) that are medically necessary for members at nutritional risk when:

- The formula is the predominant source of the member's nutritional intake (i.e., > 50% of the daily caloric intake); and
- The member meets the general eligibility criteria and the specific medical review criteria for enteral nutrition for one of the covered conditions listed below.

The OSU Health Plan does not cover special medical formulas and enteral nutrition solely for food preference. There must be an underlying medical condition requiring a non-traditional food source.

Unless otherwise addressed within this policy or otherwise mandated, The OSU Health Plan does not cover standard commercial formulas (e.g., Boost, Carnation Good Start, Carnation Soy, Enfamil, Ensure, Isomil, Prosobee Similac, Similac Soy), food supplements, food fortifiers, or food thickeners.

AUTHORIZATION

Prior authorization is required for all oral nutrition including special medical formulas (i.e., premature transitional formulas, extensively hydrolyzed formulas, amino acid based formulas, ketogenic formulas, and metabolic specific formulas).

Coverage requests must include pertinent clinical notes, and be submitted on the appropriate request form (available at www.osuhealthplan.com/forms-and-downloads).

GENERAL ELIGIBILITY CRITERIA:

Special medical formulas are authorized initially and subsequently when ALL the following criteria are met:

1. Detailed clinical notes and supportive testing document that the member meets one of the Covered Conditions Criteria listed below.
2. The enteral nutrition requested is the predominant source of the member's nutritional intake (i.e., > 50% of the daily caloric intake). If the member is over the age of one year, caloric counts and a nutritionist evaluation need to document that the 50% threshold is met.
3. There is documentation confirming that the requested enteral nutrition is medically necessary to prevent clinical deterioration, and that age or the medical condition precludes the use of regular food and supplementation with commercially available nutritional supplemental foods (e.g., Carnation Instant Breakfast, food thickeners, butter or cream added to prepared foods) in sufficient caloric density to provide > 50% of the member's daily caloric needs.
4. For infant and pediatric special medical formula requests:
 - a. For formula fed infants and pediatric members, both cow-milk-based and soy-based formula must have been tried for a period of time, at least 4-5 days for each trial, with the reason for failure well documented; or

- b. If the formula trial is contraindicated or not completed based on the clinical condition or clinical diagnosis (e.g., prematurity under 3 months of life, food protein-induced proctocolitis/enteropathy/enterocolitis), this rationale must be documented.
- c. For infants and pediatric members transitioning from breast milk to formula:
 - i. When the symptoms/clinical condition resolved with a well-documented and appropriate maternal elimination diet, a same protein formula trial is not required.
 - ii. If the elimination diet did not resolve the symptoms/clinical condition, a trial of milk-based and soy-based formula is required.
- 5. For members over one year of age, in addition to a nutritionist evaluation and calorie counts, either a gastroenterologist or allergist evaluation is required depending on the Covered Condition Criteria.
- 6. Formula request forms along with pertinent clinical notes must be submitted. For infants and pediatric patients, weight for age, weight for height growth charts, and BMI charts if applicable, must be submitted. For adults, BMI and/or weight measured over time must be submitted.

COVERED CONDITIONS:

Prematurity:

1. Transition formulas (e.g., Neosure, Enfacare) are authorized for premature infants up to 3 months life when documentation confirms either of the following:
 - a. Birth weight 1500g or less, and hospital discharge weight less than the 10th percentile for age corrected for prematurity; or
 - b. Intolerance to cow milk-based formula due to any of the other covered conditions.

After 3 months of life, subsequent requests are re-evaluated based on meeting general eligibility requirements and one of the other covered conditions below.

Gastroesophageal Reflux and Gastroesophageal Reflux Disease:

Special medical formulas are not usually medically necessary for gastroesophageal reflux. The regurgitation of gastric contents, is common in infants, peaks at 4-6 months of life, and generally does not need medical treatment or a change in formula. Parental reassurance, restriction of volume in overfed infants, and a trial of thickened formula generally suffice.

Special medical formulas may be medically necessary for infants with gastroesophageal reflux disease (GERD), regurgitation associated with complications and nutritional compromise (i.e., weight loss/lack of weight gain due to insufficient caloric intake/formula refusal, blood in regurgitated foods, or severe vomiting).

1. For infants with GERD, special medical formula is authorized up to the first nine months of life when the general eligibility criteria and all of the following are met:
 - a. Clinical history and physical exam document a high probability of GERD and not simply gastroesophageal reflux characterized by ALL:
 - i. Regurgitation associated with complications (e.g., blood in regurgitated foods); and
 - ii. Nutritional compromise (i.e., severe vomiting, weight loss, lack of weight gain) due to insufficient caloric intake or formula refusal.
 - b. Both cow-milk-based and soy-based formula trials have failed:
 - i. Thickened feeds should be tried as well.
 - ii. Medical therapies, such as H2-blockers or proton-pump inhibitors are at the discretion of the physician.
 - c. For infants transitioning from breast milk to formula, documentation must include evidence of an appropriate maternal elimination diet.
2. Subsequent requests for infants up to one year of life require:

- a. Evidence that they symptoms significantly improved with the use of the requested special medical formula; and
 - b. A failed retrial of both cow-milk-based and soy-based foods/formula, each for 4-5 days respectively, **or** a gastroenterologist evaluation confirms the ongoing need for the requested special medical formula.
3. Subsequent requests for children after one year of life require:
- a. Consideration of a retrial of both cow-milk-based foods/formula and soy-based formula; and
 - b. A nutritionist consult including calorie counts; and
 - c. A gastroenterologist evaluation.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Bloody Stools With or Without other GI Symptoms or Weight Loss:

Potential formula related diagnoses include the non IgE mediated: food protein-induced proctocolitis (generally healthy member with blood streaked stools), food protein-induced enteropathy (malabsorption, failure to thrive, diarrhea and vomiting), and food protein-induced enterocolitis (chronically associated with malabsorption and failure to thrive; acute reactions associated with recurrent vomiting, diarrhea, and dehydration). Common non-food related etiologies are rectal fissures and infections/inflammatory colitis.

1. Special medical formula is authorized for infants up to the first year of life when the general eligibility criteria and all of the following are met:
 - a. Bloody stools are documented by guaiac card testing; and
 - b. Other etiologies, such as anorectal fissure and infection/inflammatory colitis, have been excluded by history and exam, and when applicable, by further testing and serial guaiacs; and
 - c. The bloody stools occurred while using cow-milk-based formula, or while breast feeding, and a dairy elimination diet resolved the problem. (No soy formula trial is required because of the high cross intolerance to soy-based formula for those conditions).
2. Subsequent requests for children after one year of life require:
 - a. Unless contraindicated, retrial of commercial formulas must be considered; and
 - b. A nutritionist consult including calorie counts; and
 - c. A gastroenterologist evaluation.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

GI Irritability:

Mild to moderate GI irritability, spitting, fussiness and gassiness or loose/mucous containing stools in the absence of weight loss, lack of weight gain, significant vomiting or gastrointestinal bleeding, generally does not require a formula change.

1. For severe and persistent symptoms, special medical formula is authorized for infants up to the first 6 months of life when the general eligibility criteria are met and both cow-milk-based and soy-based formula trials each lasting at least 4-5 days, respectively, have failed.
2. Subsequent requests for infants up to one year of life require:
 - a. Evidence that the symptoms significantly improved with the use of the requested special medical formula; and
 - b. A failed retrial of either cow-milk-based and soy-based formula, each lasting 4-5 days respectively, or a gastroenterologist evaluation confirms the ongoing use of the special medical formula is reasonable and medically necessary.
3. Subsequent requests for children after one year of life require:

- a. Consideration of a retrial of both cow-milk-based and soy-based foods/formula; and
- b. A nutritionist consult including calorie counts; and
- c. A gastroenterologist evaluation.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Eosinophilic Esophagitis (EE):

Eosinophilic esophagitis rarely occurs in infants. In children it is characterized by intermittent vomiting, food refusal, dysphagia, abdominal pain and weight loss.

1. Special medical formula or other enteral nutrition is authorized when the general eligibility criteria and all of the following are met:
 - a. Eosinophilic esophagitis is documented by endoscopy and biopsy; and
 - b. For formula fed infants, there is high suspicion either by elimination diet or supportive IgE specific antibody testing that it is caused both by milk and soy exposure; or for children, the EE is caused by an unclear number of food groups and there is a planned multi-food elimination diet that includes the elimination of milk and soy; and
 - c. The member is closely followed by a gastroenterologist, and a nutritionist who documents diet and calorie needs, and by an allergist if indicated.
 - d. If all of the above criteria are met, the requested special medical formula/enteral nutrition does not need to constitute > 50% of the daily caloric intake since the goal is to provide not only calories, but also nutrients that cannot be obtained through regular foods/allergy-free-vitamins in these highly allergic members.

The period of authorization for formula/enteral nutrition depends on the member's clinical condition, timing of needed follow up visits and repeat endoscopy and biopsy documented in the clinical notes.

Subsequent requests require documentation of intervening medical and nutritional reassessments and follow up endoscopy to determine if the clinical condition has improved enough to allow intake of other nutrients and to document calorie counts.

Malabsorption:

Malabsorption in infants and children can be associated with chronic diarrhea and weight loss, and may be secondary to food protein-induced enteropathy or enterocolitis (acute enterocolitis reactions are associated with recurrent vomiting, diarrhea, and dehydration), or to non-food related etiologies as well.

1. Special medical formula is authorized for infants up to the first year of life when the general eligibility criteria and all of the following are met:
 - a. Causes of the malabsorption have been evaluated and the diagnosis of food protein-induced enteropathy or enterocolitis is confirmed by a pediatric gastroenterology evaluation; and
 - b. The malabsorption symptom occurred while using cow-milk-based formula, or while breast feeding a dairy elimination diet resolved the problem. (No soy formula trial is required when food protein-induced enteropathy or enterocolitis is diagnosed because of the high cross intolerance to soy-based formula for this condition).
2. Subsequent requests for members after one year of life require:
 - a. A consideration for a retrial of cow-milk-based and soy-based food/formula; and
 - b. Continued evaluation by a gastroenterologist and a nutritionist.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

3. For malabsorption with nutritional compromise in children and adults associated with such conditions as Crohn's disease, ulcerative colitis, gastrointestinal motility disorders, chronic intestinal pseudo-obstruction or cystic fibrosis, enteral nutrition is authorized for up to a period of 6 months when the general eligibility criteria and all of the following are met:
 - a. The diagnosis is confirmed by testing; and
 - b. Nutritional compromise is documented by weight loss/lack of weight gain or other nutritional deficiencies; and
 - c. For formula fed infants and children, both cow-milk-based and soy-based formula trials have failed; and
 - d. If applicable, the member must have first attempted supplementation with other commercially available foods and nutritional supplemental foods (e.g., Carnation Instant Breakfast, food thickeners, butter or cream added to prepared foods, etc.); and
 - e. The member is being closely followed by gastroenterology and a nutritionist.

Subsequent requests for authorization require documentation of intervening clinical and nutritional reassessments to determine if the clinical condition has improved sufficiently to allow intake of other nutrients and to document calorie counts. The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Failure to Thrive:

The diagnosis includes growth failure due to inadequate nutrient intake or absorption, increased nutritional losses, or ineffective nutrient utilization. The failure to thrive diagnosis does not automatically include infants and children with intrauterine growth restriction, prematurity, and genetic short stature when the member otherwise has appropriate growth velocity and is tracking along a weight for length growth curve even if it is less than 2nd percentile.

Special medical formula/enteral nutrition is authorized for up to a period of 6 months when the general eligibility criteria and all of the following are met:

1. The member is at nutritional risk with one of the following weight loss parameters:
 - a. For infants and children age 0 – 24 months, ANY of the following:
 - i. Decrease over time of two or more major weight for age percentile lines; or
 - ii. Weight < 5th percentile for age when corrected for prematurity; or
 - iii. Weight for length < 10th percentile.
 - b. For children and adolescents (aged 2 – 18 years), a BMI for age < 5th percentile; or
 - c. For adults, ANY of the following:
 - i. An involuntary weight loss of > 10 percent of usual body weight during a three-to-six-month period
 - ii. BMI < 5th percentile or 18.5 kg/m².
 - d. For members with cystic fibrosis and weight loss, a weight for length/height or BMI < 25th percentile is considered sufficient to meet the weight loss parameter.
 - e. For members on renal dialysis, either weight loss with a BMI of < 22, or a falling serum albumin to < 4 g/dl is considered sufficient to meet the weight loss parameter.
2. There must be documentation of:
 - a. Clinical history, physical exam and supportive testing to evaluate potential treatable causes of growth failure; and
 - b. For formula fed infants and children, a failure of both cow-milk-based and soy-based formula trials; and
 - c. If a supplement to formula is being requested or for members over one year of age, a detailed dietary/feeding history with calorie counts and referral to a nutritionist; and
 - d. If applicable, the member must have first attempted supplementation with other commercially available foods and nutritional supplemental foods (e.g., Carnation Instant Breakfast, food thickeners, butter or cream added to prepared foods, etc.); and

- e. For member's over one year of age, documentation/results of relevant specialist evaluation(s), such as gastroenterology, feeding/swallowing specialist, or other specialist evaluations; and
- f. A written plan of care for regular monitoring of signs and symptoms to detect improvement in the member's condition.

Subsequent requests for authorization require intervening clinical and nutritional reassessments to determine if the clinical condition has improved sufficiently to allow intake of other nutrients and to document calorie counts.

The authorization period for the formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

IgE Mediated Food Allergy:

Symptoms include the following: severe vomiting and abdominal pain within minutes to hours of the ingestion; severe diarrhea within six hours of the ingestion; localized or general pruritis, angioedema and urticarial; stridor, wheezing; anaphylaxis. GI symptomatology generally does not occur in isolation, and most often is associated with involvement in other organ systems.

1. Special medical formula is authorized for infants up to the first year of life when the general eligibility criteria and one of the following are met:
 - a. When a cow-milk-based formula is clearly implicated in the highly likely IgE mediated reaction, a soy-based formula trial is not required. (Although soy cross reactivity for an IgE mediated response is low at 10-15%, and the cross occurrence of anaphylaxis less than 1%); or
 - b. For members with a non-urticarial rash or with a rash and a negative IgE to soy, a failure of both cow-milk-based and soy-based formula trials is required.
2. Subsequent requests for children after one year of life require:
 - a. Consideration of a retrial of both cow-milk-based and soy-based foods/formula; and
 - b. A nutritionist consult including calorie counts; and
 - c. An allergist evaluation to further document the food allergy.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Atopic Dermatitis (AD):

Mild to moderate AD is generally not related to formula allergy even in the presence of food specific IgE antibodies. Food allergy may cause 1-3% of mild AD and 5-10% of moderate AD. For severe AD, defined as widespread skin involvement which impairs quality of life that persists despite first line medical therapy (moisturizers, wraps, topical steroids, and antihistamines), and occurring in very young infants, causal food allergy may be present in 20-30%.

1. Special medical formula is authorized for infants up to the first year of life when the general eligibility criteria are met and all of the following are met:
 - a. There is a well-documented role of both cow-milk-based and soy-based formula in causing the atopic dermatitis (e.g., an immediate reaction after ingestion or a well-defined elimination diet); and
 - b. There is an allergist evaluation confirming the formula induced atopic dermatitis.
2. Subsequent requests for children after one year of life require:
 - a. Consideration of a retrial of both cow-milk-based and soy-based food/formula; and
 - b. A nutritionist consult including calorie counts; and
 - c. Results of allergist re-evaluation to further document the food allergy.

The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

Inborn Errors of Metabolism:

These include the following diagnoses:

Phenylketonuria (PKU)	Tyrosinemia
Homocystinuria	Maple Syrup Urine Disease
Propionic Acidemia	Methylmalonic Acidemia
Other Organic Acidemias	Urea Cycle Disorders

Special formulas/enteral nutrition is authorized when a letter of medical necessity from a Metabolic Clinic documenting the clinical history, supportive evaluation and testing is submitted. Neither a milk nor a soy trial is required.

Ketogenic Formula for Uncontrolled Seizures:

1. Ketogenic formulas are authorized for up to a period of 6 months when there is clinical documentation confirming that the member:
 - a. Has seizures refractory to standard anti-seizure medications; and
 - b. Requires a formula/liquid diet to maintain weight for age growth because of inability to tolerate solid foods due to developmental or other issues (the formula requested does not need to meet > 50% of daily caloric intake).
 - c. Neither a milk nor a soy food/formula trial is required.
2. Subsequent requests for authorization require intervening clinical and nutritional reassessments to determine if the clinical condition has improved to allow intake of other nutrients and to document calorie counts. The authorization period for the subsequent formula/enteral nutrition request depends on the member's clinical condition and timing of needed follow up visits.

EXCLUSIONS

The OSU Health Plan does not cover:

1. Enteral nutrition including infant formula for indications not listed above.
2. Enteral nutrition including infant formulas when a medical history or physical examination has not been completed, and/or there is no documentation that supports the need for enteral nutrition products.
3. Enteral nutrition including infant formulas when a medical history and physical examination have been performed and other possible alternatives have been identified to minimize the member's nutritional risk.
4. Enteral nutrition including infant formulas when the member is underweight but has the ability to meet nutritional requirements through the use of regular food consumption.
5. Enteral nutrition including infant formulas when the member has food allergies or dental problems, but has the ability to meet his or her nutritional requirements through an alternative store-bought food source.
6. Standard infant milk or soy formulas;
7. Formula of food products used for dieting, or a weight-loss program;
8. Banked breast milk;
9. Food for a ketogenic diet when dietary needs can be met with regular, store-bought food;
10. Dietary or food supplements, including fortifiers (e.g., Duocal, Benecalorie);
11. Food thickeners;
12. Supplemental high protein powders and mixes;

13. Lactose free foods, or products that aid in lactose digestion;
14. Gluten-free products;
15. Baby foods;
16. Oral vitamins and minerals;
17. Medical foods (e.g., Foltx, Metanx, Cerefolin, probiotics such as VSL#3) including FDA-approved medical foods obtained via prescription.
18. Solutions not requiring a doctor's prescription (except when they are given via a tube feeding and are the primary source of nutrition), for example, Ensure and Osmolyte;
19. Regular grocery products;
20. Any supplements or formula intended for weight loss or treatment of anorexia or other eating disorders;
21. Coverage to accommodate psychological or behavioral conditions, food preferences, loss of appetite, or non-compliance with specialized diet.
22. Storage unit (e.g., refrigerator)
23. Enzyme packed cartridges (e.g., Relizorb (Alcresta Pharmaceuticals)) for enzyme replacement in patients receiving enteral tube feedings.

RELATED CPT CODES

- B4149 Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4150 Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4152 Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4153 Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4154 Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4155 Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit
- B4157 Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4158 Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
- B4159 Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
- B4160 Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4161 Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4162 Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

DIAGNOSES THAT MAY SUPPORT MEDICAL NECESSITY

Not specified – see criteria.

REFERENCES AND ATTACHMENTS

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